

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CITY OF HUNTINGTON**

**Plaintiff,**

**v.**

**AMERISOURCEBERGEN DRUG  
CORPORATION, et al.,  
Defendants.**

**Civil Action No. 3:17-cv-01362**

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**CABELL COUNTY COMMISSION,**

**Plaintiff,**

**v.**

**AMERISOURCEBERGEN DRUG  
CORPORATION, et al.,  
Defendants.**

***Consolidated Case:***  
**Civil Action No. 3:17-cv-01665**

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**PLAINTIFFS' RESPONSE TO SUPPLEMENTAL MEMORANDUM IN  
SUPPORT OF DEFENDANTS' RENEWED *DAUBERT* MOTION TO  
EXCLUDE THE EXPERT OPINIONS OF JAMES E. RAFALSKI**

Plaintiffs submit this response to address the new arguments raised in Defendants' Supplemental Memorandum in Support of their Renewed *Daubert* Motion to Exclude the Expert Opinions of James E. Rafalski (ECF No. 1405) ("Suppl. Memo."). Neither of Defendants' two new arguments supports exclusion.

*First*, Defendants contend that the testimony of Joseph Rannazzisi "fatally undermined," Suppl. Memo. at 1, the methodology Mr. Rafalski used in forming his opinions on their Suspicious Order Monitoring ("SOM") programs and the flagged orders they improperly shipped without adequate due diligence. It did not. Just the opposite, Mr. Rannazzisi's testimony underscores the reliability of Mr. Rafalski's methodology and opinions.

Defendants’ argument once again improperly conflates two distinct legal duties under the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* (“CSA”), and Drug Enforcement Administration (“DEA”) regulations governing their distribution activity. First, Defendants must maintain “effective controls and procedures to guard against theft and diversion of controlled substances.” 21 C.F.R. § 1301.71(a). Second, they also must design and operate a system to identify and report “suspicious orders” to the DEA. 21 C.F.R. § 1301.74(b). Simply put, Mr. Rafalski’s expert testimony addresses the first of these duties, the duty to maintain effective controls against diversion, while Mr. Rannazzisi’s testimony relied upon by Defendants addresses the second, the duty to report suspicious orders to the DEA.

That Mr. Rafalski’s expert opinions address the duty to maintain effective controls against diversion is abundantly clear from his testimony. *See* 5/26 Tr. at 15:24-16:5 (position at DEA was “Diversion investigator”); *id.* at 30 (offered as “expert in the field of diversion control investigations, Suspicious Order Monitoring Systems, and maintenance of effective control to prevent diversion of controlled substances into the illicit market”). Mr. Rafalski’s opinions about flagged orders that Defendants should have investigated and not shipped unless and until the flag was resolved are based on the duty to maintain effective controls:

*The maintenance of effective controls to prevent diversion is what’s the key issue here* in that the company has – has – takes this held order and they make a decision on whether they’re going to ship it.

Part of that decision process is commonly called due diligence. It’s an internal investigation where they look at some internal information and facts and circumstances, take some action as warranted, and the company would make a decision.

If they believe that this suspicion is dispelled, that dispels the potential for diversion, then that order would flow down to the customer and also be reported to ARCOS.

If in fact they conduct this investigation and they can't clear or dispel the suspicion, then that order would be blocked and cancelled *and* it would be reported to the DEA.

*Id.* at 76:2-20. As Plaintiffs have made clear, *see* Opposition (ECF No. 1396) at 13-14, Mr. Rafalski's opinion that the duty to maintain effective controls means that flagged orders and all subsequent orders by the same customer should not be shipped unless and until the red flag is resolved finds support in Defendants' own SOM programs. *See* 5/13 Tr. at 75:13-76:21 (*ABDC*); 5/20 Tr. at 95:4-97:5 (*Cardinal*); P-12627-00001 and P-42536-00001 (*McKesson*).

By contrast, Mr. Rannazzisi's testimony on which Defendants rely addresses the separate § 1301.74(b) duty to report suspicious orders to the DEA. *See* 6/8 Tr. at 109:9-111:24 (addressing Defendants' reporting duty); 6/9 Tr. at 80:25-81:17 (same). Moreover, to the extent Mr. Rannazzisi testified that the reporting duty requires Defendants to have more information than just that the order exceeded a threshold—that it requires factual context showing why the order is suspicious—this is consistent with Mr. Rafalski's testimony. *Compare* 6/9 Tr. (Rannazzisi) at 81:7-17 (“[T]hey were supposed to explain what created the suspicious nature of the order which is basically due diligence. . . . A suspicious order is not just, oh, it's over the threshold. . . . There's got to be something just – threshold, that's exactly what due diligence is. It's looking at a suspicious order above threshold. There's got to be some reason it's above threshold.”); *with* 5/26 Tr. (Rafalski) at 76:9-20

(“Part of that decision process is commonly called due diligence. It’s an internal investigation where they look at some internal information and facts and circumstances, take some action as warranted, and the company would make a decision. . . . If, in fact, they conduct this investigation and they can’t clear or dispel the suspicion, *then* that order would be blocked and cancelled and it would be reported to the DEA.”). Mr. Rannazzisi’s testimony thus only underscores the reliability of Mr. Rafalski’s expert opinions.

*Second*, Defendants also contend that Mr. Rafalski’s expert opinions must be excluded unless Plaintiffs re-call Dr. Craig McCann to testify about the work he did in applying Mr. Rafalski’s methodologies to quantify Defendants’ orders that were improperly shipped. *See* Suppl. Memo. at 2-3. This, too, is incorrect.

As Plaintiffs have argued and the Court recognized in denying Defendants’ attempts to block Mr. Rafalski’s testimony without Dr. McCann first testifying, *see* 5/20 Tr. at 8:8-12 and 13:17-22, Mr. Rafalski may testify based on facts or data that are not or even *could not be* admitted so long as they are of a type reasonably relied upon in his field. Fed. R. Evid. 703. While Plaintiffs had originally planned to re-call Dr. McCann, the Court admitted Mr. Rafalski’s opinions during his testimony over Defendants’ objection that Dr. McCann’s testimony was a prerequisite:

I’m going to cut this short and rely on Rule 703, which the first sentence says an expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. He’s been aware of this data that comes from Dr. McCann, apparently, or is consistent with what Dr. McCann said and I think that since it’s the basis of an expert opinion, it’s permissible, and I’m going to overrule the objection and let him go ahead.

5/26 Tr. at 53:10-21. Rule 703's other foundational requirement -- that "experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject" -- was established by Mr. Rafalski's unrefuted testimony. *See* 5/26 Tr. at 114:25-115:6.

Defendants now seek to turn Rule 703 on its head. They argue that Mr. Rafalski cannot provide expert opinion testimony on their failures to maintain effective controls unless Dr. McCann also testifies to establish the admissibility of Mr. Rafalski's underlying data. In so arguing, Defendants rely upon two cases involving unusual facts that other courts frequently distinguish, and that indeed are readily distinguishable from those presented here.

In *Tokio Marine & Fire Ins. Co., Ltd. v. Norfolk & W. Railway Co.*, 172 F.3d 44, 1999 WL 12931 (4th Cir. Jan. 14, 1999) (unpublished op.), the Court addressed whether an appraisal of the salvage value of damaged automobiles could be admitted as an expert opinion where the person who determined the appraisal values (Clark) was unavailable to testify, but his grandson who assisted him (Wisecup) testified instead. *Id.* at \*2. The Fourth Circuit held that this was not a permissible expert opinion because the appraisal containing the opinion was prepared by Clark, whom the plaintiff had no opportunity to cross-examine.<sup>1</sup> This decision thus is readily distinguishable from cases like this one where an expert

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<sup>1</sup> *Id.* at \*4 (Tokio Marine "did question Wisecup as to what he saw Clark doing when the two men examined the cars. However, since the final valuation opinion was exclusively Clark's, the cross-examination of Wisecup could reveal nothing about the mental processes by which Clark reached his opinion.").

(Mr. Rafalski) formulates his own opinions on the subject matter based in part upon data provided by others (Dr. McCann).<sup>2</sup>

So, too, is the Seventh Circuit’s decision in *Matter of James Wilson Assocs.*, 965 F.2d 160 (7th Cir. 1991), readily distinguishable from the facts presented here and frequently distinguished by other courts. In *Wilson*, the court affirmed the trial court’s exclusion of an architect’s attempt to provide an expert opinion on a building’s structural soundness based on an engineer’s examination. *See* 965 F.2d at 172. While noting that an “expert is, of course, permitted to testify to an opinion formed on the basis of information that is handed to rather than developed by him—information of which he lacks first-hand knowledge and which might not be admissible in evidence . . . [.]” *id.*, the court held that the architect could not offer an engineering opinion that merely parroted the engineer’s analysis.<sup>3</sup>

In light of these exceptional facts, numerous courts have rejected arguments attempting to analogize to *Wilson*, as Defendants do here. In *Factory Mut. Ins. Co. v. Alon USA, LP*, 705 F.3d 518 (5th Cir. 2013), the court explained that “[t]he

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<sup>2</sup> *See, e.g., Hi-Tech Pharms., Inc. v. Dynamic Sports Nutrition, LLC*, 2021 WL 2185699, at \*8 (N.D. Ga. May 28, 2021) (in *Tokio Marine*, “the witness who sought to give expert testimony conceded that the opinions in the report belonged exclusively to someone else, and the witness merely agreed with that person’s opinion. . . . Here, however, Dr. Fontana’s testimony provides details and insights into the testing procedures and the mental processes by which he concluded that androstenedione, DHEA, and DHT were present in the DIANABOL® sample.”).

<sup>3</sup> *See id.* at 173 (“The architect could use what the engineer told him to offer an opinion within the architect’s domain of expertise, but he could not testify for the purpose of vouching for the truth of what the engineer had told him—of becoming in short the engineer’s spokesman.”).

problem [in *Wilson*] was rooted in the fact that the architect was seeking to repeat information on a topic outside of his expertise instead of using ‘what the engineer told him to offer an opinion within the architect’s domain of expertise . . . .’” *Id.* at 525 n.5 (quoting *Wilson*, 965 F.2d at 173). The court then found that “[t]his case is distinguishable, however, since Miles sought to use information outside of the employees’ expertise to offer an opinion within his own expertise.” *Id.*<sup>4</sup> This is just what Mr. Rafalski did here—offer opinions within his own expertise on Defendants’ diversion-control systems, which are based in part upon data given by Dr. McCann, *whose analysis and calculations were made using Mr. Rafalski’s methodologies.*

Likewise, the fact that Mr. Rafalski could not testify about the design choices Dr. McCann used to quantify Mr. Rafalski’s methods, does not prevent Mr. Rafalski from relying on Dr. McCann. *See, e.g., Edwards v. Ethicon, Inc.*, No. 2:12-CV-

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<sup>4</sup> *See also In re Suboxone Antitrust Litig.*, 2020 WL 6887885, at \*5 (E.D. Pa. Nov. 24, 2020) (distinguishing *Wilson*, finding that expert “made his own observations and formed his own opinions about what the FDA Form 482 demonstrated, and turned to his colleagues solely for consultation and confirmation of opinions he independently formed.”); *see also id.* at \*6 (“Dr. Fleischer’s reliance upon his colleagues to confirm his already-formulated conclusion does not constitute a basis for exclusion. ‘An expert may expand his or her knowledge by consulting colleagues and journal articles. *To hold otherwise would be to require scientists to develop all of their knowledge through their own clinical work or experiments. This is an unrealistic expectation and it ignores the reality of science as a collaborative process.*’”) (quoting *Adel v. Greensprings of Vt., Inc.*, 363 F. Supp. 2d 683, 692 (D. Vt. 2005)) (emphasis added); *Wilhelm v. Ameristep Corp.*, No. 7:15-CV-00362, 2018 WL 6272911, at \*6 (W.D. Va. Nov. 30, 2018) (following the death of expert who had conducted testing, court concluded that “[t]o the extent Wilhelm’s other experts rely on Dr. Jerner’s report, however, and to the extent such reliance is consistent with the practice in these experts’ respective fields, the court concludes that it is appropriate to allow a discussion of his findings or opinions through those other experts.” (citing Fed. R. Evid. 703)).

09972, 2014 WL 3361923, at \*21 (S.D.W. Va. July 8, 2014) (“But an expert witness is not required to be familiar with the particular details of each of the studies on which he bases his opinion, as long as an expert in that particular field reasonably relies on the opinions contained in those studies.”). Defendants cite no authority for the claim, Suppl. Memo at 3-4, that Dr. McCann’s calculations must be presented by him and subject to cross-examination. Where, as here, reasonable reliance by experts in the field has been shown, the fact that “an expert relies on the opinion of another . . . goes to the weight, not to the admissibility of the expert's opinion.”

*Edwards, supra* (quoting *Ferrara & DiMercurio v. St. Paul Mercury Ins. Co.*, 240 F.3d 1, 9 (1st Cir.2001)).<sup>5</sup>

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<sup>5</sup> The Fourth Circuit’s decision in *United States v. Cuong*, 18 F.3d 1132 (4th Cir. 1994), comports with the foregoing. In *Cuong*, the Court excluded the expert opinion of a family physician who adopted wholesale the opinions in a forensic report prepared by a general surgeon who did not testify or otherwise appear in the case. *See id.* at 1143 (“When asked if his conclusions were contrary to those of Dr. Stevenson, the witness responded, ‘No. My findings were essentially the same.’”). In addressing Rule 703, the Court questioned whether the testifying expert, Dr. McIntosh, “usually relies upon forensic medical opinions or reports in forming his opinions in his field of expertise—family medicine.”). The Court’s ruling, however, differentiated between a testifying expert’s *permissible* reliance on information obtained from another expert, and their impermissible adoption of the other expert’s opinions. *See id.* (“Dr. McIntosh could testify that he reviewed Dr. Stevenson’s report and that he relied upon it in reaching his opinion, but he could not say that the two opinions or reports were essentially the same without calling Dr. Stevenson as a witness and putting his report into evidence.”); *see also Collins v. Cottrell Contr. Corp.*, 733 F. Supp. 2d 690, 701 (E.D.N.C. 2010) (“As already noted, an expert may rely on the work of another expert in forming his opinion without impermissibly ‘adopting’ the other expert’s opinion.”). Mr. Rafalski’s opinions based upon Dr. McCann’s data generated using Mr. Rafalski’s own methodologies clearly are examples of what is permissible. Moreover, unlike the expert in *Cuong*, Mr. Rafalski testified that experts in his field, including DEA diversion investigators whose work by its nature includes civil and criminal litigation, rely on experts like



Notably, in spite of having had the opportunity to cross-examine Dr. McCann at least six times, Defendants cannot point to any inaccuracies in his calculations. Simply put, the law is clear -- Mr. Rafalski's opinions are admissible with or without Dr. McCann's corroborating testimony.

Finally, the Court also should reject Defendants' argument that Plaintiffs waived the right to not re-call Dr. McCann. *See* Suppl. Memo. at 5 ("[W]hen Defendants asked that Dr. McCann be recalled to provide his flagging methodology testimony ***before*** Dr. Rafalski could testify about that methodology, Plaintiffs successfully opposed that request by representing to the Court that Mr. Rafalski could give his testimony under the doctrine of conditional relevance because Plaintiffs would be recalling Dr. McCann.") (emphasis in original). This account is incomplete, and thus incorrect.

Plaintiffs first raised conditional relevancy in opposition to Defendants' attempt to force Plaintiffs to re-call Dr. McCann before Mr. Rafalski testified. *See* 5/19 Tr. at 231:18-21 ("We think the good order is the one we've proposed and we would suggest that under [Rule] 104(b), conditional relevancy, that the sequence is appropriate for us to put on both of them in that order."). The Court *rejected* Plaintiffs' argument. *Id.* at 234:17-18 ("Well, I'm going to ask you to call Dr. McCann first, Mr. Farrell."). Plaintiffs the next day sought reconsideration based in part upon Rule 703. *See* 5/20 Tr. at 8:8-9 ("Third, Rule 703 governing experts states

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Dr. McCann to assist them in providing data to support their opinions. 5/26 Tr. at 114:25-115:1-6.

that experts can rely on inadmissible data.”). The Court granted this request. *See id.* at 13:17-19 (“I’ve given this a good bit of thought last night and I think the plaintiffs do have a right to control their case.”). Moreover, as noted above, when Defendants persisted in trying to prevent Mr. Rafalski from testifying as to information provided by Dr. McCann, the Court again rejected their argument, relying expressly upon Rule 703. 5/26 Tr. at 53: 13-21. Once the Court made this ruling, there was no need to recall Dr. McCann. The Court ruled correctly in allowing this testimony based upon Rule 703, and Plaintiffs did not waive this argument that the Court adopted.

### **CONCLUSION**

For all of the reasons set forth herein and in Plaintiffs’ Opposition, the Court should deny Defendants’ renewed motion to exclude Mr. Rafalski’s expert opinions.

Dated: June 16, 2021

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on June 16, 2021, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

/s/ Anthony J. Majestro